

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

OREXO AB,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC. and  
MYLAN INC.,

Defendants.

Civil Action No. 3:11-cv-3788-FLW-LHG

Hon. Freda L. Wolfson, U.S.D.J.

Hon. Lois H. Goodman, U.S.M.J.

Motion Return Date: August 20, 2012

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**BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.  
AND MYLAN INC.'S MOTION TO SEAL PORTIONS OF THE JULY 6, 2012 LETTER  
AND EXHIBITS TO THE JULY 8, 2012 LETTER (ECF NOS. 64 AND 65)**

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**TABLE OF CONTENTS**

	<b><u>Page</u></b>
TABLE OF AUTHORITIES .....	ii-iii
PRELIMINARY STATEMENT .....	1
STATEMENT OF FACTS .....	2
ARGUMENT.....	3
POINT I .....	3
THE APPLICABLE LEGAL STANDARDS FOR A MOTION TO SEAL .....	3
POINT II.....	4
UNDER LOCAL CIVIL RULE 5.3(c)(2)(B), LEGITIMATE INTERESTS WARRANT THE SEALING OF THIS INFORMATION .....	4
POINT III.....	6
UNDER LOCAL CIVIL RULE 5.3(c)(2)(C), SERIOUS INJURY WOULD RESULT IF THE CONFIDENTIAL INFORMATION WERE NOT SEALED.....	6
POINT IV.....	6
UNDER LOCAL CIVIL RULE 5.3(c)(2)(D), NO LESS RESTRICTIVE ALTERNATIVE IS AVAILABLE .....	6
CONCLUSION.....	7

## TABLE OF AUTHORITIES

<b>Cases</b>	<b><u>Page</u></b>
<u>Goldstein v. Forbes (In re Cendant Corp.)</u> , 260 F.3d 183 (3d Cir. 2001).....	3
<u>In re Gabapentin Patent Litig.</u> 312 F. Supp. 2d 653 (D.N.J. 2004).....	4, 5
<u>Littlejohn v. BIC Corp.</u> , 851 F.2d 673 (3d Cir. 1988).....	3, 4
<u>Miller v. Indiana Hosp.</u> 16 F.3d 549 (3d Cir. 1994).....	3
<u>Nixon v. Warner Commc'ns, Inc.</u> , 435 U.S. 589 (1978).....	4
<u>Pansy v. Borough of Stroudsburg</u> , 23 F.3d 772 (3d Cir. 1994).....	6
<u>Publicker Indus. Inc. v. Cohen</u> , 733 F.2d 1059 (3d Cir. 1984).....	3, 6
<u>Republic of the Philippines v. Westinghouse Elec. Corp.</u> , 949 F.2d 653 (3d Cir. 1991).....	4
<u>Vista India, Inc. v. Raaga, LLC</u> 2008 WL 834399 (D.N.J. Mar. 27, 2008).....	4-5
<u>Zenith Radio Corp. v. Matsushita Fleet Indus. Co. Ltd.</u> 529 F. Supp. 866 (E.D. Pa. 1981) .....	3
<b>Rules</b>	
21 C.F.R. § 314.430(b)-(d) .....	2, 5
Local Civil Rule 5.3(c) .....	1, 3
LOCAL CIVIL RULE 5.3(c)(2)(B).....	4
LOCAL CIVIL RULE 5.3(c)(2)(C).....	6
LOCAL CIVIL RULE 5.3(c)(2)(D) .....	6
Fed. R. Civ. P. 26(c)(1)(G) .....	3

**Miscellaneous**

Restatement (Second) of Torts § 757 comment b.....	5
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**PRELIMINARY STATEMENT**

Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, “Mylan”) (collectively, “Mylan”) respectfully submit this Brief in support of their Motion, pursuant to Local Civil Rule 5.3(c), to Seal the following portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter (ECF Nos. 64 and 65):

July 6, 2012 Letter

- Page 4, last paragraph, line 3;
- Page 5, lines 6-7;
- Attachment to July 6, 2012 letter, Table of Disputed Terms, Rows 2-7, Column 2, all constructions except “Treatment” and “Effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles”;

Exhibit B to the July 8, 2012 letter

- Page 2, Attachment 2, Row 3, Column 2, lines 1-5;
- Page 3, Attachment 2, Row 2, Column 2, lines 22-23;
- Page 6, Attachment 3, Row 3, Column 2, lines 5-22;
- Page 7, Attachment 3, Row 2, all of Column 2;
- Page 8, Attachment 3, Row 2, Column 2, lines 1-7, 9-15;
- Page 28, Attachment 3, Row 2, Column 2, line 27;
- Page 29, Attachment 3, Row 2, all of Column 2;
- Page 30, Attachment 3, Row 2, Column 2, lines 1-17;

Exhibit D1 to the July 8, 2012 letter

- Table, all constructions except “treatment” and “effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles”; and

Exhibit D2 to the July 8, 2012 letter

- Table, Row 3, Columns 2-5.

(collectively, the “Confidential Information”). These documents reveal information that Defendants have marked as Confidential – Outside Counsel’s Eyes Only, prior to the entry of the Discovery Confidentiality Order in this case. After the entry of the Discovery Confidentiality Order, the parties agreed that the information would be treated as “Highly Confidential” pursuant to the Discovery Confidentiality Order entered by the Court in this matter.

The Confidential Information contains and/or reflects Abbreviated New Drug Application (“ANDA”) information and proprietary business information regarding the formulation and manufacture of Mylan’s ANDA product. Mylan’s proprietary formulation and manufacturing information is presently confidential and otherwise unavailable to the public, and disclosure of this Confidential Information could seriously impair and injure Mylan’s competitive posture in the marketplace. Recognizing this potential injury, federal law requires that an ANDA remain confidential. See 21 C.F.R. § 314.430(b)-(d)).

Accordingly, it is respectfully requested that the Court grant Mylan’s Motion to Seal for the reasons set forth herein.

### **STATEMENT OF FACTS**

Mylan respectfully incorporates herein the factual details set forth in the Proposed Findings of Fact and Conclusions of Law submitted herewith regarding the Confidential Information sought to be sealed herein. Those facts demonstrate the basis for sealing the Confidential Information that is the subject of this motion.

## **ARGUMENT**

### **POINT I**

#### **THE APPLICABLE LEGAL STANDARDS FOR A MOTION TO SEAL**

There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record bears the burden of demonstrating that “the material is the kind of information that courts will protect.” Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus. Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)). This Court has the power to seal where confidential information may be disclosed to the public. In particular, Fed. R. Civ. P. 26(c)(1)(G) provides for the courts’ protection of materials containing “trade secret[s] or other confidential research, development, or commercial information[.]” upon motion by a party, to prevent harm to a litigant’s competitive standing in the marketplace. See Zenith Radio Corp. v. Matsushita Fleet Indus. Co. Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (a) the nature of the materials or proceedings at issue;
- (b) the legitimate private or public interest which warrants the relief sought;
- (c) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (d) why a less restrictive alternative to the relief sought is not available.

The Confidential Information that is the subject of this Motion relates to Mylan's commercially sensitive and/or proprietary non-public trade secret and technical information. Specifically, the Confidential Information contains and/or reflects proprietary business information regarding the formulation and manufacture of Mylan's ANDA product.

## **POINT II**

### **UNDER LOCAL CIVIL RULE 5.3(c)(2)(B), LEGITIMATE INTERESTS WARRANT THE SEALING OF THIS INFORMATION**

Courts have recognized that the public right of access to judicial proceedings and records is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). "Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes." Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)). Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citation omitted).

The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted). As such, a party's confidential processes, chemical formulas and specifications, and research information should be sealed. Id. at 667-68; see Vista India, Inc. v.



Raaga, LLC, 2008 WL 834399, at \*2 (D.N.J. Mar. 27, 2008) (protecting “any formula, pattern, device, or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it”) (ultimately quoting Restatement (Second) of Torts § 757 comment b).

Indeed, information included in an ANDA often consists of trade secrets, and federal law requires that ANDAs remain confidential. See Gabapentin, 312 F. Supp. 2d at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party’s confidential processes, chemical formulas and specifications, and research information should be sealed. Gabapentin, 312 F. Supp. 2d at 667-68.

The private interests at stake in this action warrant the relief sought. Here, plaintiff and defendants – private parties – are in dispute relating to a patent and a generic drug product. Sealing the identified documents as requested herein serves to protect the private proprietary business interests of Mylan, which has a legitimate interest in ensuring that its confidential and proprietary non-public trade secrets, business and technical information remain undisclosed. If this information were to become publicly available, then Mylan’s competitors could potentially (and likely) use that information in the highly competitive pharmaceutical product marketplace. Therefore, the release of Mylan’s Confidential Information poses a substantial risk of harm to Mylan’s legitimate business interests and competitive position. Indeed, the federal government has recognized this interest by requiring that Mylan’s ANDA remain confidential.

**POINT III**

**UNDER LOCAL CIVIL RULE 5.3(c)(2)(C), SERIOUS INJURY WOULD RESULT IF  
THE CONFIDENTIAL INFORMATION WERE NOT SEALED**

This Court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994). Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

If relief is not granted, Mylan's designated highly sensitive and confidential trade secrets will be compromised, exposing it to substantial risks. Unless the Confidential Information is filed under seal, competitors and others will have access to Mylan's important confidential proprietary trade secrets, business and confidential information that ordinarily would not be available to the public, let alone to Mylan's competitors in the highly-competitive pharmaceutical industry. Competitors and others in the marketplace might exploit such information to their advantage and benefit, and to Mylan's unfair detriment.

**POINT IV**

**UNDER LOCAL CIVIL RULE 5.3(c)(2)(D), NO LESS  
RESTRICTIVE ALTERNATIVE IS AVAILABLE**

Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. This concern must be balanced with the requirement that only the "least restrictive alternative" be utilized to restrict public access to judicial proceedings. Publicker, 733 F.2d at 1073.

No less restrictive alternative to sealing is available because Mylan's request is tailored to seal only those portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter from

which may be discerned the confidential material discussed during the proceedings – specifically, that information containing or relating to its ANDA – the release of which would pose a financial and competitive risk to Mylan. Accordingly, the only way to protect Mylan’s confidential interest is to seal the specific portions of the July 6, 2012 letter and exhibits to the July 8, 2012 letter identified herein.

### **CONCLUSION**

For the foregoing reasons, Mylan respectfully requests that the Court recognize that there is no other remedy available but to seal the Confidential Information as requested above.

Dated: July 16, 2012

Respectfully submitted,

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